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10/807,016	03/23/2004	David Feygin	115-004US	4798

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EXAMINER	
FRISBY, KESHA	
ART UNIT	**PAPER NUMBER**
3714	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/807,016	FEYGIN ET AL.	
	Examiner	Art Unit	
	Kesha Frisby	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

As a result of the Amendment After Final being filed on 9/18/2007, claims 1-40 are pending.

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-3, 6-23, 25-27 & 35-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Cunningham et al. (U.S. Publication Number 2003/0069719).

Referring to claim 1, Cunningham et al. discloses pseudo skin (skin traction mechanism 36); a receiver (shaft 44), wherein said receiver receives an end effector; and a first device (casing 127) for performing a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure, wherein said receiver and said first device are disposed beneath said pseudo skin (Fig. 3 and the associated text).

Referring to claim 2, Cunningham et al. discloses wherein an insertion region for said

end effector is defined at a site at which said end effector is received by said receiver, and wherein said insertion region is proximal to a first region of said pseudo skin (Fig. 3 & the associated text).

Referring to claim 3, Cunningham et al. discloses wherein: said first skin-interaction technique comprises at least one of either palpation or occlusion (paragraphs 0046 & 0052); a second region of said pseudo skin is accessible to perform said first skin-interaction technique; and said first region of said pseudo skin is closer to a user than said second region of said pseudo skin when said user is using said apparatus (Figs. 3 & 4).

Referring to claim 4, Cunningham et al. discloses further comprising a second device (Fig. 4 & the associated text) for performing a second skin-interaction technique, wherein said second device is disposed beneath said pseudo skin (Figs. 3, 4 & the associated text).

Referring to claim 6, Cunningham et al. discloses further comprising a housing (catheter unit assembly 34), wherein said housing has an anterior portion (catheter needle assembly), a posterior portion (shaft 44), an upper surface (catheter needle assembly 47 & shaft 44) and a lower surface (housing 50) wherein, in use: said anterior portion is proximal to a user (Fig. 4); said posterior portion is distal to said user (Fig. 4); said lower surface is proximal to a support surface (base 60) on which said apparatus resides (Fig. 4); and said upper surface is distal to said support surface (Fig. 4).

Referring to claim 7, Cunningham et al. discloses wherein said upper surface is no more than about 5 inches above said lower surface (Fig. 4).

Referring to claim 8, Cunningham et al. discloses wherein said housing comprises at least one opening proximal to said upper surface thereof to access said pseudo skin (Fig. 3).

Referring to claim 9, Cunningham et al. discloses wherein said housing comprises a handle proximal to said anterior portion by which a user grips said apparatus during use (needle handle 48).

Referring to claim 10, Cunningham et al. discloses wherein: an insertion region for said end effector is defined at a site at which said end effector is received by said receiver (paragraph 0040); said insertion region is proximal to a first region of said pseudo skin (Fig. 3); and a first end of said receiver is relatively closer to said insertion region and a second end of said receiver is relatively further from said insertion region (Fig. 4).

Referring to claim 11, Cunningham et al. discloses wherein: said first skin-interaction technique comprises at least one of either palpation or occlusion (paragraphs 0046 & 0052); and said first end of said receiver is closer to said anterior portion of said housing than said first device (Fig. 4).

Referring to claim 12, Cunningham et al. discloses wherein: said first skin-interaction technique comprises at least one of either palpation or occlusion (paragraphs 0046 & 0052); and an upper-most surface of said first device extends a greater distance above said lower surface of said housing than said first end of said receiver (Fig. 4).

Referring to claim 13, Cunningham et al. discloses further comprising a second device for performing a second skin-interaction technique, wherein said second device is disposed beneath said pseudo skin (Figs. 3, 4 & the associated text).

Referring to claim 14, Cunningham et al. does not disclose wherein:

said first skin-interaction technique comprises one of either palpation or occlusion (paragraphs 0035, 0046 & 0052); and said second skin-interaction technique comprises skin-stretch (paragraph 0046).

Referring to claim 15, Cunningham et al. discloses wherein at least some portion of said second device is closer to said anterior portion of said housing than said first device (Fig. 4).

Referring to claim16, Cunningham et al. discloses wherein at least some portion of said second device is closer to said anterior portion of said housing than said first end of said receiver (Fig. 4).

Referring to claim 17, Cunningham et al. discloses wherein said first end of said receiver is closer to said anterior portion of said housing than said first device (Fig. 4).

Referring to claim18, Cunningham et al. discloses wherein an upper-most surface of said first device extends a greater distance above said lower surface of said housing than said first end of said receiver (Fig. 4).

Referring to claim 19, Cunningham et al. discloses wherein an upper-most surface of said first device extends further above said lower surface of said housing than an upper-most surface of said second device (Fig. 4).

Referring to claim 20, Cunningham et al. discloses wherein at least a portion of said receiver is disposed beneath an upper-most surface of said first device (Fig. 4).

Referring to claim 21, Cunningham et al. discloses further comprising an electronics/communications interface (communication interface 24), wherein: said

electronics/communications interface receives signals from sensors that are associated with at least one of said first device or said receiver (paragraph 0054); and said electronics/communications interface is disposed beneath said pseudo skin (paragraph 0054).

Referring to claim 22, Cunningham et al. discloses wherein said electronics/communications interface is closer to said posterior portion of said housing than said first device (paragraph 0054, Figs. 3 & 4).

Referring to claim 23, Cunningham et al. discloses wherein said electronics/communications interface is closer to said posterior portion of said housing than said receiver (paragraph 0054, Figs. 3 & 4).

Referring to claim 24, Cunningham et al. discloses wherein said electronics/communications interface comprises a printed circuit board, and further wherein a major surface of said printed circuit board is disposed orthogonal to an uppermost surface of said first device (paragraph 0054, Figs. 3 & 4).

Referring to claim 25, Cunningham et al. discloses a housing (catheter unit assembly 34); an end effector (catheter 47), wherein said end effector is inserted into said housing during the performance of a simulated vascular-access procedure (Figs. 3 & 4); and a plurality of mechanisms (pulleys 112 & 115), wherein said plurality of mechanisms are contained completely within said housing (Figs. 3 & 4), and wherein said plurality of mechanisms include: (a) a first mechanism (casing 127) is for simulating a first skin-interaction technique that is used in conjunction with a simulated vascular-access procedure; and (b) a second mechanism (shaft 44) for receiving said end effector.

Referring to claim 26, Cunningham et al. discloses wherein: said housing (catheter unit assembly 34), has a longitudinal axis (Fig. 3); a first end of said longitudinal axis defines an anterior portion of said housing (catheter needle assembly 47); a second end of said longitudinal axis defines a posterior portion of said housing (shaft 44); and in use, said anterior portion is proximal to a user and said posterior portion is distal to said user (Fig. 4).

Referring to claim 27, Cunningham et al. discloses wherein said plurality of mechanisms are disposed beneath a pseudo skin (Figs. 3 & 4).

Referring to claim 35, Cunningham et al. discloses a pseudo skin (36); a plurality of mechanisms with which a user interacts for simulating a vascular- access procedure (pulleys 112, 115), wherein said plurality of mechanisms are disposed under said skin; and a housing (30), wherein said housing contains said plurality of mechanisms (Figs. 3 & 4).

Referring to claim 36, Cunningham et al. discloses wherein said housing is no more than about 5 inches in height (Figs. 3 & 4).

Referring to claim 37, Cunningham et al. discloses wherein said housing is no more than about 4 inches in height (Figs. 3 & 4).

Referring to claim 38, Cunningham et al. discloses wherein at least one of either a needle or catheter is disposed outside of said housing until inserted therein during a simulated vascular-access procedure (Figs. 3 & 4).

Referring to claim 39, Cunningham et al. discloses further comprising a data processing

system, wherein said data processing system receives signals from sensors that are associated with said plurality of mechanisms (paragraph 0054).

Referring to claim 40, Cunningham et al. discloses wherein said plurality of mechanisms comprise discrete devices, wherein a first of said devices (casing 127) is for enabling a user to perform a skin-stretch technique, a second of said devices (shaft 44) is for receiving a needle or catheter or both, and a third of said devices (paragraphs 0035, 0046 & 0052) is for enabling a user to perform at least one of either a palpation technique or an occlusion technique.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 5 & 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. in view of Liu et al. (U.S. Publication 2003/0210259).

Referring to claim 5, Cunningham et al. discloses the apparatus of claim 4 and wherein: said second skin-interaction technique comprises skin stretching (paragraph 0052), a

region of said pseudo skin is accessible to perform said second skin-interaction technique (Figs. 3 & 4); and said region of said pseudo skin is closer to a user than said first region of said pseudo skin when said user is using said apparatus (Figs. 3 & 4). Cunningham et al. does not disclose. *Cunningham et al. does not disclose a third region.* However, Liu et al. teaches a third region (230, 240 & 250). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a third region, as disclosed by Cunningham et al., incorporated into Liu et al. in order to determine the different forces, pressures or textures in different regions.

Referring to claim 28, Cunningham et al. discloses the apparatus of claim 25 and wherein said end effector is at least one of either a needle or a catheter (Figs. 3 & 4) (claim 28). *Cunningham et al. does not disclose wherein said mechanisms include a third mechanism for simulating a second skin-interaction technique.* However, Lui et al. teaches wherein said mechanisms includes a third mechanism for simulating a second skin-interaction technique. (230, 240 & 250). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a third region, as disclosed by Cunningham et al., incorporated into Liu et al. in order to determine the different forces, pressures or textures in different regions.

Referring to claim 29, Cunningham et al., as modified by Lui et al., discloses wherein: said first skin-interaction technique is skin-stretch (paragraph 0052 of Cunningham et al.); said second skin-interaction technique is at least one of either palpation or occlusion (paragraphs 0035, 0046 & 0052 of Cunningham et al.); and at least a portion said first mechanism is disposed at a substantially different position along said

longitudinal axis than said second mechanism and said third mechanism (Fig. 4 of Cunningham et al.).

Referring to claim 30, Cunningham et al., as modified by Lui et al., discloses wherein: said first skin-interaction technique is skin-stretch (paragraph 0052 of Cunningham et al.); said second skin-interaction technique is at least one of either palpation or occlusion (paragraphs 0035, 0046 & 0052 of Cunningham et al.); and said first mechanism is closer to said anterior portion of said housing than said second mechanism and said third mechanism (Fig. 4 of Cunningham et al.).

Referring to claim 31, Cunningham et al., as modified by Lui et al., discloses wherein: said first skin-interaction technique is skin-stretch (paragraph 0052 of Cunningham et al.); said second skin-interaction technique is at least one of either palpation or occlusion (paragraphs 0035, 0046 & 0052 of Cunningham et al.); and at least a portion said second mechanism is disposed at a substantially different position along said longitudinal axis than said first mechanism and said third mechanism (Fig. 4 of Cunningham et al.).

Referring to claim 32, Cunningham et al., as modified by Lui et al., discloses wherein: said first skin-interaction technique is skin-stretch (paragraph 0052 of Cunningham et al.); said second skin-interaction technique is at least one of either palpation or occlusion (paragraphs 0035, 0046 & 0052 of Cunningham et al.); and said third mechanism is closer to said posterior portion of said housing than said first mechanism and said second mechanism (Fig. 4 of Cunningham et al.).

Referring to claim 33, Cunningham et al., as modified by Lui et al., discloses wherein

said portion of said second mechanism is flanked by said first mechanism and said third mechanism along said longitudinal axis (Figs. 3, 4 & the associated text of Cunningham et al.).

Referring to claim 34, Cunningham et al., as modified by Lui et al., discloses wherein: a user interacts with said first mechanism at a first site at an upper surface of said housing; said user interacts with said second mechanism at a second site at said upper surface of said housing; said user interacts with said third mechanism at a third site at said upper surface of said housing; and a position of each of said first site, second site, and third site along said longitudinal axis corresponds to said positions of said respective first mechanism, second mechanism, and third mechanism along said longitudinal axis (Figs. 3, 4 & the associated text of Cunningham et al.).

Response to Arguments

7. Applicant's arguments filed 9/18/2007 have been fully considered but they are not persuasive. In response to the applicant's arguments in regards to Function/Use limitations the examiner stated that claim language after the word "for" in apparatus claim is nothing more than intended use. The claim language after the word "for" must be considered, however, this statement applies when considering functional language for purposes of applying prior art. While features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. MPEP 2114

8. Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kesha Frisby whose telephone number is 571-272-8774. The examiner can normally be reached on Mon. - Wed. 7-3pm & Thurs. - Fri. 7-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ronald Laneau
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Art Unit 3714
10/4/07

Kyf
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